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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,606	05/08/2001	Rubinah K. Chowdhary	273012011700	4962

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EXAMINER
KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
1615	11

DATE MAILED: 03/27/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/851,606	Chowdhary
Examiner	**Art Unit**
Gollamudi Kishore	1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 22, 2003* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-30* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-30* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The request for the extension of time and amendment filed on 1-22-03 are acknowledged.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless -**
>
> **(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.**

2. Claims 29 is rejected under 35 U.S.C. 102(b) as being anticipated by Madden (5,389,378).

Madden discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note Examples). The formulations are enclosed in a capsule (exo-support).

> **(e) the invention was described in-**
> **(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or**
> **(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).**

3. Claims 29 is rejected under 35 U.S.C. 102(e) as being anticipated by Desai (6,074,666).

Desai discloses a method of preparation of lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note columns 6-7, Examples and claims, claim 8 in particular).

These rejections are maintained since 29 is an independent claim and does not recite the requirement of the copolymer.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

5. Claims 1-20 and 27-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Lentini (5,885,557) or Young (6,375,930) in further combination with either Unger (6,028,066) or Desai (6,074,666) or Madden (5,389,378).

Lentini, and Young both disclose that photodynamic therapy could be practiced with photosensitizing material in carriers such as micelles and liposomes (note the abstract,

col. 7, line 62 through col. 8, line 29 of Lentini; abstract, col. 11, line 33 through col. 13, line 43).

What is lacking in Lentini and Young is the teachings of the inclusion of a saccharide such as trehalose and polymers such as PEG and polyvinyl pyrrolidone and freeze-dry the composition to a solid state.

Unger while disclosing the formulations containing liposomes and micelles for therapeutic and diagnostic purposes teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose are added (note the abstract, col. 4, lines 9-58 and col. 79, lines 45-57).

As pointed out in the previous action, Desai discloses lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport) for photodynamic therapy (note columns 6-7, Examples and claims, claim 8 in particular) and Madden discloses lyophilized powders containing a phospholipid, a benzoporphyrin and lactose (endosupport and a protective sugar) for photodynamic therapy (note Examples). The formulations are enclosed in a capsule (exo-support)..

To include sugars such as trehalose and lyophilize the preparations of Lentini or Young would have been obvious to one of ordinary skill in the art because Unger teaches that lyophilized compositions have advantage of greater shelf life and to prevent the agglutination as a result of lyophilization, additives such as glucose and trehalose and

polymers such as PEG and polyvinyl pyrollidone are added; the inclusion of sugars would have also have been obvious to one of ordinary skill in the art since these are protective agents according to Madden and these are routinely added in freeze dried preparations containing photosensitizers according to Desai.

Applicant's arguments have been fully considered, but are not found to be persuasive. Applicant provides no specific arguments with regard to Lentini or Young except to agree with the examiner as to what is lacking in these references. Applicant argues that Unger does not correct the deficiencies of Lentini or Young since according to applicant, the description of additives on col. 79, lines 45-57 are in sufficient even though glucose, trehalose, polyvinyl pyrrolidone and PEG are included. This is because, according to applicant, these 'additives' are used to prevent agglutination or fusion of the lipids and/or vesicles as opposed to being the carrier agent or the solid support as recited in the originally filed claims. This argument is not found to be persuasive since motivation to add the additional material need not be the same as applicant's. Applicant's arguments with regard to small amounts of glucose or trehalose as an additive to prevent agglutination is not the same as using it as solid support as recited in claims 9 and 10 or mere inclusion of small amounts of polyvinyl pyrrolidone or PEG as an additive to prevent agglutination is not the same as using it as carrier agent in instant claims are not persuasive since instant claims do not recite any amounts for these agents.

Applicant argues that claim 1 has been amended to recite 'block copolymer carrier agent and Unger is the only one of the three references cited which even mentions the term, 'poloxamer' on col. 40, lines 50-55, but this is in context of using it as an emulsifying and/or solubilizing agent as opposed to carrier agent per se are not persuasive since as pointed out above, the motivation to add this agent need not be the same as applicant's.

6. Claims 21-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Lentini (5,885,557) or Young (6,375,930) in further combination with Unger (6,028,066) or Desai (6,074,666) or Madden (5,389,378) as set forth above, further in view of Kataoka (Journal of controlled Medicine, 1993) of record.

The teachings of Lentini, Young, Unger, Desai, and Madden have been discussed above. What is lacking in these references is the teaching of the use of instant block polymers.

Kataoka teaches that using polyoxyethylene-polyoxypropylene block polymers for the preparation of micelles and subsequent use for drug delivery have advantages such as high carrying capacity for the hydrophobic drugs, simple sterilization by micro filtration and prolonged storage in a freeze-dried state (note the abstract and Table 1).

The use of the block polymers as the material in the preparation of micelles of Lentini, Young, Unger, Desai, Madden would have been obvious to one of ordinary skill in the art because of the advantages of these polymers as taught by Kataoka.

Applicant's arguments with regard to Lentini, Young and Unger have been addressed above. Applicant argues that Kataoka does not teach any solid support for physical association withe the mixture of a photosensitizer and a block copolymer. This argument is not found to be persuasive since although Kataoka's reference does not teach photosensitizers, it provides a clear motivation to include the block polymers in compositions containing micelles in a freeze-dried state. With regard to solid support, the examiner points out that the references of Unger, Desai, and Madden teach the sugars (solid support). Applicant's arguments that there is no disclosure by Kataoka of micelle formation using a block copolymer that is not conjugated to a (photosensitizer) molecule to be sequestered within a micelle are not found to be persuasive since instant claim language 'comprising' does not exclude such a conjugate. Furthermore, according to instant claim 1, the composition is defined as containing both a) and b) (photosensitizer/ block polymer; a solid support) and this composition forms a complex. In addition, the examiner points out that Kataoka clearly states that the block copolymer as a vehicle for drug delivery which implies any drug and that the polymer is a carrier agent. The examiner also directs applicant's attention to col. 1, page 123 where Kataoka states that the polymeric micelles can be prepared either by physical entrapment or covalent binding.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.

Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

March 25, 2003